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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,050	11/19/2003	Michael Yeadon	1/1346	3489

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MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY RD
P O BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER	
CHONG, YONG SOO	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,050	YEADON, MICHAEL	
	Examiner	Art Unit	
	YONG S. CHONG	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *5,11-19,25 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10,20-24,26-31,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's response filed on 11/29/2007. Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged.

The traversal is on the grounds that a restriction requirement has already been made. This is not found persuasive because it is within the Examiner's right to withdraw, modify, or make a new restriction requirement as warranted, especially since the claims have not been examined on the merits yet. Further traversal is made on the grounds that the Groups do not encompass the full scope of the claims as it relates to other embodiments of dopamine D2-receptor agonists other than the ones listed in Groups IA to IAA. This is found not persuasive because the dopamine D2-receptor agonists other than the ones listed in Groups IA to IAA have already been restricted in the first restriction requirement therefore being drawn to a non-elected group. Further traversal is made on the grounds that sufficient basis has not been provided for restricting between Groups A to W in the first restriction requirement and Groups IA to IAA of the second restriction requirement since all the compounds are dopamine D2-receptor agonists. This is found not persuasive because even though these compounds are apparently dopamine D2-receptor agonists, there is no common structural core among the compounds. Therefore, a search for one will not lead to the search for another in the non-patent literature from a structural standpoint. One would not look for a particular compound using the search term "dopamine D2-receptor agonist" rather a

direct search on the structure of the compound is more efficient. Furthermore, even though Markush groups are proper, it is only accepted from the standpoint that the Markush group does not contain more than one patentably distinct compound. Further traversal is made on the grounds that Groups I-IV only relate to embodiments where the tiotropium is of formula (1.1.1), however other anti-cholinergics have not been encompassed for election. This is found not persuasive because the instant claims do not recite any anti-cholinergics other than the ones encompassed by formula (1.1.1). Finally, the last traversal is made on the grounds that there is no evidence to suggest the process can be practiced with a materially different product. This is found not persuasive because one of ordinary skill in the art knows that avoiding asthma triggers and using a drug regimen including bronchodilators is a well-accepted method for treating asthma.

The requirement is still deemed proper and is therefore made FINAL. Claim(s) 1-34 are pending. Claim(s) 5, 11-19, 25, 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim(s) 1, 2-4 (in part), 6-10, 20-22, 23-24 (in part), 26-31, 33-34 are examined herein insofar as they read on the elected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 1-4, 6-10, 20-24, 26-31, 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "selected from the group consisting of tiotropium and pharmaceutically acceptable salts, anions, isomers, isotopes, polymorphs, hydrates, and solvates thereof" in claim 1 renders the claim indefinite as it is not clear whether the composition comprises (1) tiotropium only or (2) a combination of tiotropium and a pharmaceutically acceptable salt, anion, isomer, isotope, polymorph, hydrates, or solvate thereof. Examiner notes that the Markush recitation should be in alternative form and singular.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1, 2-4 (in part), 6-10, 20-22, 23-24 (in part), 26-31, 33-34 are rejected under 35 U.S.C. 103(a) as being obvious over Banerjee et al. (US Patent Application 2002/0151598 A1).

The instant claims are directed to a composition comprising pramipexole (dopamine D2-receptor agonist) and tiotropium of formula 1.1.1 (anti-cholinergic agent).

Banerjee et al. teach the treatment, prevention, or amelioration of bronchoconstrictive disorders (abstract). In a specific embodiment, a dopamine D2-receptor agonist and an anticholinergic agent is administered in combination with formoterol (paragraph 0076). A preferred dopamine D2-receptor agonist is pramipexole (paragraph 0078) and a preferred anticholinergic agent is tiotropium bromide at a concentration of 5 µg/mLto 5 mg/mL (paragraph 0080). The teaching of tiotropium bromide meets the structural limitations found in claims 6-10, 26-30, and 33. Pharmaceutically acceptable derivatives of a compound used herein include salts, such as hydrochlorides (paragraph 0029). The methods involve administering an effective amount of a pharmaceutical composition provided herein to a subject in need of such treatment (paragraph 0014). It is understood that the compounds for use in the compositions and methods provided herein may contain chiral centers. Such chiral centers may be either the (R) or (S) configuration, or may be a mixture thereof (paragraph 0033). The compositions are intended for administration as a nebulized

aerosol (abstract). Examples of pharmaceutical packing materials include inhalers (paragraph 0088) for example propellant-based metered dose inhalers and dry powerder does inhalers (paragraph 0040).

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

However, Banerjee et al. fail to disclose a composition comprising the specific combination of pramipexole and tiotropium.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have specifically combined pramipexole and tiotropium in the composition disclosed by Banerjee et al.

A person of ordinary skill in the art would have been motivated to have specifically combined pramipexole and tiotropium in the composition disclosed by Banerjee et al. because: (1) Banerjee et al. disclose a specific embodiment comprising a dopamine D2-receptor agonist and an anticholinergic agent in combination with formoterol; (2) Banerjee et al. disclose pramipexole as a preferred dopamine D2-receptor agonist; and (3) Banerjee et al. disclose tiotropium as a preferred anticholinergic agent. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating bronchoconstrictive disorders by administering a composition comprising pramipexole and tiotropium as taught by Banerjee et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC